

Application No.: 10/563,314
Filing Date: August 1, 2006

REMARKS

Claims 1-19 and 21 are currently pending. Claims 1-19 and 21 stand rejected under 35 U.S.C. § 103 as unpatentable over U.S. Patent No. 6,365,205 to Wahlgren. The Examiner also cited “Approximate pH of foods and Food Products, hereafter ‘pH’” and “US Dairy Export Council-Nutritional Information, hereafter USDEC” as evidence.

It is well settled that the Examiner “bears the initial burden of presenting a *prima facie* case of unpatentability...” *In re Sullivan*, 498 F.3d 1345 (Fed. Cir. 2007). Until the Examiner has established a *prima facie* case of obviousness, the Applicant need not present arguments or evidence of non-obviousness. To establish a *prima facie* case of obviousness, the Examiner must establish at least three elements. First, the prior art reference (or references when combined) must teach or suggest all of the claim limitations: “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F.2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970); *see also* M.P.E.P. § 2143.03. Second, there must be a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986); *Pharmastem Therapeutics v. Viacell, Inc.*, 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007); *see also* M.P.E.P. § 2143.02. And finally, the Examiner must articulate some reason to modify or combine the cited references that renders the claim obvious. Merely establishing that the claimed elements can be found in the prior art is not sufficient to establish a *prima facie* case of obviousness.

Wahlgren Fails to Disclose the Features of the Claims

Applicants submit that Wahlgren fails to disclose the features of the claims. The Examiner found Wahlgren to disclose pasteurizing a dairy starting material (col. 2, lines 41-42). It appears that the Examiner found the pasteurization step of Wahlgren to read on the cooking step recited in the claims.

Applicants respectfully disagree that the pasteurization step of Wahlgren is a cooking step as recited in the claims. Wahlgren describes a process for preparing a water continuous dairy ingredient with a fat content of 13-27%, the process involving acidification of cream with at least 25% fat. Abstract. Wahlgren discloses pasteurization at 70°C before or after homogenization.

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Col. 2, lines 41-42. Wahlgren also uses a temperature of 70°C in the examples. Col. 5, line 22; see also Examples 1-7.

The skilled artisan would recognize that the pasteurization step in Wahlgren and the cooking step, as recited in the claims, serve different purposes. A person of skill in the art would understand the pasteurization in Wahlgren to be a process specifically designed to slow microbial growth and thereby minimize possible health hazards arising from pathogenic microorganisms. The skilled artisan would also understand that pasteurization is designed to minimize chemical, physical and organoleptic changes to the treated milk and dairy products.

The cooking step as claimed, serves a different purpose from the pasteurization step of Wahlgren. The cooking step is used to modify the casein whey interaction. (See paragraph [0046] of the specification as published, "Preferred cooking times may be chosen on the basis that they are times sufficient for modification of the casein whey interaction. Casein-whey interactions provided by the cooking step provide increased strength of the texture of products produced from the casein whey mixture relative to uncooked controls or controls cooked at a pH of approximately 5.7.")

Accordingly, a skilled artisan would recognize that the pasteurization of Wahlgren is not a cooking step as claimed, because cooking is designed to substantially modify the chemical, physical, and organoleptic properties of the dairy product, while the process of Wahlgren is intended to kill microorganisms without changing the nature of the product.

Thus, for the reasons discussed above, Wahlgren fails to disclose "subjecting the material with the desired pH to a cooking step" as recited in Claims 1 and 19.

Further, this is more than an obvious variation of the pasteurization step of Wahlgren. Pasteurization processes result in minimal denaturation of whey proteins and minimal functional changes to dairy products other than microbial inactivation and shelf life extension. The temperature for pasteurization disclosed in Wahlgren of 70°C is not high enough to cause the denaturation of the proteins required for the structural modifications of the whey proteins used in Wahlgren. Further in support of this point, Applicants attach articles from Kessler and Beyer ("Thermal denaturation of whey proteins and its effect in dairy technology, Int. J. Biol. Macromol., 1991, Vol. 13, pages 165-173) and Dannenberg and Kessler ("Reaction Kinetics of

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the Denaturation of Whey Proteins in Milk", Journal of Food Science, Volume 53, No. 1, 1988, pages 258-263).

For example, the article by Kessler and Beyer teaches that very little denaturation of the whey proteins takes place during pasteurization at 72°C. ("No deposit is formed during pasteurization because this takes place at 72°C at which temperature there is no noticeable b-LG denaturation." Page 171 at col. 2). Figure 6 of Kessler and Beyer illustrates the effect of heat treatments at various temperatures on the denaturation of β -lactoglobulin B. As shown in Figure 6, little denaturation occurs at temperatures around 70°C.

The article by Dannenberg and Kessler also supports that the skilled artisan would expect relatively little denaturation at temperatures around 70°C. For example, Figures 1 and 2 illustrate the denaturation for various holding times and temperatures for β -lactoglobulin B and α -lactoalbmin, respectively. Both figures illustrate that very little denaturation of whey proteins takes place at 70°C, such as the conditions for pasteurization disclosed in Wahlgren.

Accordingly, the process of Wahlgren doesn't provide functional change. Moreover, there is no reason to modify the process of Wahlgren and its pasteurization step to use a heat treatment step with the higher temperatures that are required to denature the whey proteins because Wahlgren is not interested in changing the proteins – only in pasteurization that kills microorganisms. The skilled artisan would expect a higher temperature to make functional and structural changes to the protein that are undesirable for a pasteurization step, such as the pasteurization step in Wahlgren, which is, again, designed to minimize changes to milk or dairy materials while killing microorganisms.

Additionally, Wahlgren is concerned with preventing syneresis, which is the leakage of whey. See col. 3, line 61 to col. 4, line 5. Wahlgren discloses solving this problem by homogenization (col. 4, lines 2-5), adding caseinate (Example 4, col. 6, lines 14-21), or adding gelatin (col. 6, lines 30-39). In contrast, Applicants use the cooking step to avoid syneresis. Thus, there is no reason to use a cooking step in the process of Wahlgren because Wahlgren discloses using homogenization and adding caseinate or gelatin to avoid syneresis.

Accordingly, for the reasons discussed above, Applicants respectfully submit that Wahlgren fails to make the pending claims obvious.

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No Reasonable Expectation of Success

Additionally, one skilled in the art would have no reasonable expectation of success for modifying the proteins in the pasteurization step of Wahlgren, and no expectation of success in getting the final product of Wahlgren if modifying the process the use temperatures that change the nature of the product. *Pharmastem Therapeutics v. Viacell, Inc.* 491 F.3d 1342, 83 U.S.P.Q.2d 1289 (Fed. Cir. 2007) (after KSR, Federal Circuit finds claims non-obvious for lack of indication of reasonable expectation of success for asserted combination). As discussed above, pasteurization at 70°C would not be expected to denature a significant amount of whey proteins, in contrast to the recited cooking step. This is supported by the data disclosed in the technical papers by Kessler and Beyer and Dannenburg and Kessler. Therefore, Applicants respectfully request withdrawal of the rejections for at least this reason.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

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By: David K. Buckingham

David K. Buckingham
Registration No. 60,695
Attorney of Record
Customer No. 20,995
(415) 954-4114

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